Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) PUBLIC HEALTH DATA SYSTEMS TASK FORCE 2022 MEETING

October 5, 2022, 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Gillian Haney	**Council of State and Territorial Epidemiologists (CSTE)**	**Co-Chair**
Arien Malec	**Change Healthcare**	**Co-Chair**
Rachelle Boulton	Utah Department of Health and Human Services	Member
Hans Buitendijk	Oracle Cerner	Member
Heather Cooks-Sinclair	Austin Public Health	Member
Charles Cross	Indian Health Service	Member
Steven Eichner	Texas Department of State Health Services	Member
Joe Gibson	CDC Foundation	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Erin Holt Coyne	Tennessee Department of Health, Office of Informatics and Analytics	Member
Jim Jirjis	HCA Healthcare	Member
John Kansky	Indiana Health Information Exchange	Member
Bryant Thomas Karras	Washington State Department of Health	Member
Steven Lane	Health Gorilla	Member
Jennifer Layden	Centers for Disease Control and Prevention (CDC)	Member
Leslie Lenert	Medical University of South Carolina	Member
Hung S. Luu	Children's Health	Member
Mark Marostica	Conduent Government Health Solutions	Member
Aaron Miri	Baptist Health	Member
Alex Mugge	Centers for Medicare & Medicaid Service	Member
Stephen Murphy	Network for Public Health Law	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Jamie Pina	Association of State and Territorial Health Officials (ASTHO)	Member
Abby Sears	OCHIN	Member

Name	Organization	Role
Vivian Singletary	Task Force for Global Health	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Carelon Digital Platforms (an Elevance Health company)	Member
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director of the Office of Technology
Dan Jernigan	Centers for Disease Control and Prevention	Deputy Director for Public Health Science and Surveillance
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Hsiu Wu	Centers for Disease Control and Prevention	Presenter
Christina Bradenburg	MA DPH	Presenter
Abigail Viall	Centers for Disease Control and Prevention	Discussant

Call to Order/Roll Call (00:00:07)

Michael Berry
And good morning, everyone. I am Mike Berry with ONC, and I would like to thank you for joining the Public Health Data Systems Taskforce. We do have a few guest presenters with us today, and I would like to thank them for their participation. All of our taskforce meetings are open to the public, and your feedback is always welcomed, either in the Zoom chat or during the public comment period that is scheduled about 11:50 Eastern Time this morning. I am going to begin roll call with our taskforce members, so when I call your name, please indicate that you are here, and I will start with our cochairs. Gillian Haney?

Gillian Haney
Present, good morning.

Michael Berry
I do not see Arien Malec online, but he should be joining us shortly. Rachelle Boulton?

Rachelle Boulton
Here.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Heather Cooks-Sinclair?

Heather Cooks-Sinclair
Here.

Michael Berry
Erin Holt Coyne?

Erin Holt Coyne
Good morning.

Michael Berry
Charles Cross?

Charles Cross
Good morning.

Michael Berry
Steve Eichner?

Gillian Haney
I think Steve texted he is going to be a bit late.

Michael Berry
Right, thank you. Joe Gibson?

Joe Gibson
Morning.

Michael Berry
Raj Godavarthi? Jim Jirjis? John Kansky?

John Kansky
Good morning.

Michael Berry
Bryant Thomas Karras? Steven Lane?

Steven Lane
Good morning.

Michael Berry
Jennifer Layden? Leslie Lenert? Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
Mark Marostica?

Mark Marostica
Good morning.

Michael Berry
Aaron Miri? Alexandra Mugge? Stephen Murphy?

Stephen Murphy
Good morning.

Michael Berry
Eliel Oliveira?

Eliel Oliveira
Good morning.

Michael Berry
Jamie Pina?

Jamie Pina
Present, good morning.

Michael Berry
Abby Sears?

Abby Sears
Good morning.

Michael Berry
Vivian Singletary? Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
And Sheryl Turney?

Sheryl Turney
Good morning.

Michael Berry
Good morning, everyone. Thank you so much, and now, please join me in welcoming Gillian for her opening remarks. Gillian?

Gillian Haney
Thank you. Good morning, everybody, and welcome to our seventh meeting. I am going to actually sort of skip over my opening remarks this morning so that we can get to our panelists, and then ensure that we have got plenty of time for what I am sure will be a really robust discussion and have an opportunity to start reviewing some of the comments in the worksheets and developing consensus as we move forward with our draft recommendations. So, today, we are here to talk about the sixth of the F criteria, the transmission to public health agencies and to make microbial use and antibiotic resistance reported. And, this is a bit of a unique criterion in that there is more than one data transmission that is in play here. So, we have data that are going from healthcare providers to the National Healthcare Safety Network, NHSN, and those are focused on a specific infection type as they are sent up to the national level, and then we also have data that are coming through directly to jurisdictions that are case-based reporting on individuals who may have an antibiotic-resistant infection.

We also have data that are collected in the aggregate in the form of antibiogram data, as well as individual large provider system use, and those are also coming to jurisdictions in a variety of different methods. So, there is a lot to unpack here, and it is, as I said, different from a single-stream reporting like we have in

place for electronic laboratory reporting or cancer reporting, and so, we should keep that in mind as we are listening to presentations and initiating discussions.

So, for our panelists this morning, we have two presenters, and they will be followed by someone who I think will be joining us a little bit later who will also be able to speak to their perspective from a healthcare provider, and first up, we have Christina Bradenburg from the Massachusetts Department of Public Health and Dr. Hsiu Wu from the CDC. So, welcome to you both, and I am not sure who was supposed to be speaking first. Hsiu Wu, welcome. You have the floor.

(f)(6) Transmission to Public Health Agencies – Antimicrobial use and Resistance Reporting (00:04:42)

Hsiu Wu

Okay, sure. Good morning, everyone. My name is Hsiu Wu. I am a medical epidemiologist and AUR team lead. Today, I am going to give you an overview about the CDC's National Health Safety Network for NHSN. So, NHSN launched the antimicrobial user resistance, or AUR, module, first, the antimicrobial use option, or AU option, in 2011, and later, the AR option in 2014. The AU and AR reporting was added to the MU3 program as a reporting option under public health registry in January 2017. Next slide, please.

The NHSN AUR module receives data that are extracted from hospital information systems and submitted by facilities directly to the NHSN. After data submission on NHSN application, the users can compare their data against national benchmarks as well as perform data visualizations. These functionalities are available for individual facilities and group users such as state and local health departments. The CDC can also use these data to generate national statistics. Next, please.

CDC NHSN's requirement for data submission is from the hospitals that have proper source of data, which include the admission, discharge, and transfer, or ADT, system, and for AU, those have electronic medication administration record, or EMAR, or barcoding medication administration, or BCMA, systems. For AR, those have laboratory information systems, or LIS, or an electronic health record that directly connects to an LIS system. Additionally, the reporting sites must have the ability to package data using HL7 standardized clinical document architecture, or CDA. This can be done by their internal IT resources or by hiring commercial software vendors that are certified by the ONC's Standard Version Advancement Process, or SVAP. Next, please.

Let's take a closer look at how data are extracted and handled. First, vendors or homegrown software will map their facility's local codes to a set of standardized codes, including organism, drugs, and patient care locations. Then, vendors or homegrown software select and write records and aggregate data. Finally, software packages the data, then submits to NHSN. All these steps need to follow the NHSN AUR protocol and implementation guide. The CDA files that are not following the specified implementation guide will be rejected by the NHSN application. Next.

To make sure the implementers can correctly select and aggregate data, NHSN created the AUR synthetic data sets, or SDS, which will be used to test and validate the implementor's data processing capability. NHSN issues SDS validation ID for the vendors that pass the validation to include in their CDA files. The SDS validation ID is required for data submission. Next one.

So, we are facing several challenges. First, data quality is very important for us since systemic errors can occur with electronic reporting. We notice that terminology mapping from local codes to the standard codes is the most common source of error. The standardized terminology systems, such as LOINC and RxNorm, are not universally used across facilities. Therefore, various levels of interpretation and mapping need to be done by the facilities or the vendors. This introduces the possibility for error and inconsistency across facilities. And second, where we are moving from current state to the future state, where we want to leverage the Fast Healthcare Interoperability Resources, or FHIR, for data collection, some data elements that are required for AUR and other important surveillance are not readily available in the current FHIR environment, such as medication administration. Unless resources like medication administration are made available in FHIR APIs and are set up in a truly standardized manner, surveillance will not be able to depend on new and evolving approaches to interoperability like FHIR. Next.

And third, on the AR side of reporting, we notice that AST or any microbial accessibility testing results are not complete for some drugs in some facilities. We found it is actually because of data suppression, also known as selective or cascade reporting. This is an antimicrobial stewardship practice, which is to omit the result for certain drugs from a prescriber's view. This practice is good for stewardship, but on the other hand, it can bias surveillance results. We found that data suppression can happen on LIS, EHR, or even on the testing instruments, and if AR data are extracted from downstream of where the data suppression happens, the data are incomplete and potentially biased. Thank you.

Gillian Haney
Thank you so much, Dr. Wu. Our next presenter is Christina Bradenburg, an epidemiologist with the Massachusetts Department of Public Health. Welcome, Christina.

Christina Bradenburg
Thanks. So, again, my name is Christina Bradenburg. I am one of the epidemiologists and AGI AI analytic coordinator with the Massachusetts Department of Public Health. Go to the next slide. In Massachusetts, there are several antimicrobial resistance data sources that are used. The first are multidrug-resistant organism cases that are reported to the state health department through electronic lab reporting. This includes Enterobacterales from any source that is resistant to ertapenem, imipenem, veripenem, or doripenem. We also have Enterobacterales demonstrating carbapenemase production of KPC, MDM, OXA, IMP, or VIM, and *Candida auris*. We do not require ELR reporting but we do request isolates to be sent to the state laboratory for carbapenem-resistant *Pseudomonas aeruginosa* that are non-susceptible to sebrapime or ceftazidime, as well as carbapenem-resistant *Acinetobacter baumannii*.

We also have access to resistance data for events that are reported through NHSN's patient safety component by both our acute-care and non-acute-care hospitals. This includes central-line-associated bloodstream infections, catheter-associated urinary tract infections, and suture infections, and also, once a year, Massachusetts acute-care hospitals report aggregate antibiogram data directly to the state health department. For antimicrobial use, we have a number of our acute-care hospitals that have voluntarily provided us group access to the AU data that they are reporting to NHSN. We also have some long-term care facilities who are voluntarily reporting monthly aggregate antimicrobial starts directly to the state health department, and we have conducted analyses of outpatient antimicrobial use using all payer claims data. Go to the next slide.

This is a side-by-side comparison of the different NHSN AR data sources, and it is available on our website. We have also included a comparison to our state MDR surveillance data. All these options do provide patient-level information, but I will mention when it comes to the NHSN AU module, that is reported in aggregate, so we are not able to stratify by patient demographics. One benefit to using NHSN and state MDR data is that there are standard event and surveillance definitions that are used, so we are able to compare data across different facilities and different geographical areas within Massachusetts. We do not currently have access to AR module data in NHSN, but we have heard that starting in 2024, AR and AU module data will be required to be reported.

And, with both of those modules, AR and AU, as was mentioned earlier, the data is uploaded using clinical document architecture. It is great because there is no manual data entry, but we have heard the barrier among facilities is that they have to do that initial setup using either vendor or homegrown systems. There is also an extensive data validation process initially, as well as on an annual basis.

We do get additional resistance data through NHSN's MDRO device- and procedure-associated modules. The MDRO module reporting is simplified, but it does only include a small number of organisms. As I mentioned, with all the NHSN modules, there are standard event definitions, which is great because there are national benchmarks that facilities and the states can compare their data to, but one thing we have to keep in mind is that only infections that actually do meet those definitions would actually be reported into NHSN and would have resistance data available.

For these three modules, facilities do have the option to manually enter data into NHSN, but we have heard that that is quite a burden on infection control programs at the facilities. We have heard that some of our Massachusetts hospitals have worked with their IT departments in order to actually upload data using either CDA or CSV files, but we know that is not universal among all of our facilities.

To quickly touch on our Massachusetts surveillance data, the source is comprehensive for carbapenem-resistant organisms NSIORIS. However, state epidemiologists do conduct manual filtering of lab results because it is difficult for facilities to set up an algorithm that exactly matches our reporting requirements for sending those susceptibility data to the state health department via ELR. As mentioned earlier, facilities do have access to data reported in NHSN, and there are a number of reports that they can generate within the system, and we also know that they work really closely with their laboratory and pharmacy partners to review internal reports during quality improvement meetings.

For our required and voluntary reporting, the state health department does provide feedback reports to facilities. For the NHSN AU data that facilities are voluntarily reporting, we do send reports on a biannual basis so that they can see what they have actually reported compared to state data that all our facilities that have conferred rights to us. We also send long-term care facilities quarterly reports that summarize the antibiotic start data that they are reporting to us. Again, this compares the data that they have submitted compared to aggregate data among the facilities that are participating in the program, and we also do summarize the MDRO surveillance data we collect by distributing a quarterly aggregate state summary to facilities. I think with that, I will stop. Thank you.

Discussion (00:17:36)

Gillian Haney
Thank you very much to Dr. Wu and Christina. I really appreciate that. I think you really put forth the complexities with these data, and there is a really critical need right now to be collecting these data and making use of them, but I think that there are some real opportunities to make some recommendations about potentially moving towards a reduced proprietor burden as well as making some recommendations about how the origin of these data are captured and sent. So, let's bring it open to discussion. Les, I see your hand is raised.

Leslie Lenert
Sure. I just wanted to talk a little bit about whether there are plans to transition this reporting structure to FHIR and what those look like. Obviously, CCD is great, and NHSN has been one of the leaders in provisioning of automated data from health systems, but the landscape is changing, and the document architecture is probably not where the puck will be in five years. So, what are the thoughts on that, and what are CDC's and public health's plans?

Gillian Haney
I think we heard from Dr. Wu that there are some concerns about the rapid uptake from FHIR because some data are not readily available, such as medications. Dr. Wu, do you want to speak further about that?

Hsiu Wu
Yeah, sure. So, with the current version of AUR surveillance, we received some feedback from the field that because of the limited data element, and data is currently collected and aggregated on the AU side, so we are not able to do some patient-level risk adjustment, so we are really looking into and have high hopes for FHIR, but when we took a closer look, we found that first, medication administration is not a readily available data element in the FHIR environment, as well as some other patient-level data elements are not standard in the FHIR environment, but we are still looking. Hopefully, in the future, certification or standards can guide the facilities in collecting the elements that we need for AUR. That is our next step to move AUR to the FHIR environment.

Leslie Lenert
So, you are working on that, but you think that there are still gaps in the ability to read MAR records inside of FHIR. Do you have some academic partners or other people you are working with to redefine that? I would suspect that inside of any commercial electronic records now, with the emphasis on FHIR interfaces, that interrogation of getting at medication administration is not an issue. I would have thought it was more an issue, perhaps, with getting at antibiotic susceptibility profiles or other things because maybe the standards need to be extended in those areas so that we have better representations of that within FHIR. Are there any places where you would like to see standards extended?

Hsiu Wu
Our first step is to look into AU. So, we have not done extensive evaluations of the AR part yet, and other **[inaudible] [00:21:51]** modules are thinking of getting patient-level data by FHIR, like several patient-level and facility admission, discharge, and transfer systems for the denominators are considered, and we are working with several collaboration sites on exploring and evaluating the visibility and the terminology, and we do see several potential barriers. When we start to pilot with these collaboration sites, we will see a

clearer picture of what exactly the data elements are not, like we can have a list. So far, we know that medication administration is not available on the AUR side. That is what I am the most concerned about.

Leslie Lenert
Are you working with the Helios initiative to see how bulk FHIR could be utilized to provision data in this setting?

Hsiu Wu
I am not familiar with that. Is that an organization?

Leslie Lenert
It is one of CDC's initiatives, but it is in OSILS.

Hsiu Wu
Sorry, can you say that again?

Leslie Lenert
Helios is a CDC initiative. It is in OSILS.

Hsiu Wu
Oh. I will look into that.

Gillian Haney
Thank you, Les. Abigail, I see you have your hand up.

Abigail Viall
Yeah, just a couple of things. So, actually, Leslie, it is sometimes a matter of who is on the phone. So, Andrea Bennett, who is the chief of our surveillance branch where AU/AR is housed, is familiar with Helios. To your point, and also just getting back to, frankly, some of the charge of this committee, we are trying to straddle this… When you require this of all hospitals, or at least all hospitals in the PIP, you have people who are very much on the leading edge, and then you have the folks who barely got to the CDA. And so, in some ways, we are constrained. We want to move forward, but also create a way for the laggards to come, so it is really a challenge, and the more that this committee can help us raise the floor for providers so that FHIR is not this leading, bleeding edge, it is increasingly the standard, I think that is what we are wrestling with here, but thank you, yes, we are familiar with Helios. It is just who is touching what parts of the elephant of CDC sometimes.

Gillian Haney
I know that we talk a lot about FHIR and moving towards adoption of FHIR for public health, but I think it still remains to be seen whether FHIR will really stand up for public health. I know that Helios has three different initiatives going forward in pilot projects, and hopefully we will be able to realize some of those benefits soon, but I think there is some anxiety about putting all of our eggs in one basket. Other comments or questions for the presenters? We are a quiet group today. Well, I think that will actually lend itself to good things, so we will be able to move forward to our tracker worksheet and actually spend some time reviewing some of the comments and recommendations that have been put forth. I just wanted to thank Dr. Wu and

Christina for setting the field and presenting towards us today. You are welcome to stay on the call, but you are officially released as well. So, thank you very much.

Hsiu Wu
Thank you.

Abigail Viall
Gillian, this is just one last thing. One thing that Hsiu said that you will also probably get into, as it is in your tracker, too, is this system-of-systems issue, where if we only have FHIR and standards at one part, but we are pulling from multiple systems like LIS and lab stuff, if we get one part of the system moving forward, but the other ones are not, like you mentioned public health, but I would also mention lab systems, if we are not all moving forward together, that is something that we are really challenged by, especially in a system like AU/AR, where it actually needs to pull from multiple other systems, whether directly to the EHR or separately, so I just wanted to underscore that before you guys went into this because I know that has come up, and that is kind of a key theme for us.

Gillian Haney
No, and I think the presenters both demonstrated that very clearly, about how the data are being pulled from multiple sources, and they are also being captured differently, both at the individual case level or laboratory reporting results versus aggregated data as well, so, thank you and point taken. So, I see that Liz has pulled up our tracker sheet, and I believe that my co-presenter is on. Arien?

Task Force Topics Worksheets (00:27:48)

Arien Malec
Good morning. Apologies, I slept a ridiculously long time last night, so I must still be dealing with post-COVID fatigue.

Gillian Haney
And it is also very early on the West Coast, so maybe we should acknowledge that as well.

Arien Malec
Here we are. We do schedule these things at times that I can normally be awake, but apparently, today, I was not. So, I just wanted to do a brief note in terms of process here. I have heard some concerns or some questions on the overall process, and I think most of that has been secondary to just not having time to dig through each of these recommendations, but I will take on some of the questions on process, and I would be happy to respond to any other questions that folks might have.

First of all, the general status of anything that we propose here in the spreadsheet. The goal of this material is to make it into a draft transmittal letter, and I emphasize both that this is a source material spreadsheet and that the draft transmittal is draft until roundabout early to mid-November, where it has to be near final, and we are in our final editing pass and wordsmithing, but we have a sense of our recommendations. So, this month is the month where we get into the nitty-gritty, make sure that we are carrying forward to the transmittal a set of recommendations that we generally agree on, and once we transfer information from the spreadsheet to the transmittal, it is not locked in stone at that point. It is still a draft that we will be actively engaging in, wordsmithing on, etc., but that step of transferring from the spreadsheet to the

transmittal letter really should be done with recommendations that we believe represent the consensus of the workgroup.

Second is our decisional process in all of the taskforces that I have worked on is 99% consensus-oriented, and "consensus" means that there is general agreement and no strong objection to carrying forward that these recommendations represent the opinion of the taskforce. We have had a couple of rare issues where we have had strong intra-taskforce disagreement, and we have coalesced on two potential items or two potential recommendations. In those cases, we have two options. One is just to drop the recommendation if it is not that important, if we are really arguing over the topics that are not the most material that ONC should consider. In other cases, we have gone through a formal vote and then carried two opinions, a majority opinion and a minority opinion. Sometimes, we try to make our wording very clear that is a strong and near-majority opinion, etc. I would expect those kinds of situations to be rare because our goal is to achieve consensus.

So, two really important bits. No. 1 is we aim to put forward recommendations that represent the consensus of the taskforce. We are in draft mode. The spreadsheet is an idea collection tool and the transmittal is a drafting tool, but in either of those cases, we are in draft mode until early November, in which case we are in near final mode.

We deal with disagreement generally by modifying the recommendations to the point where they address the consensus of the taskforce. For people who have gone through this type of work before, like anything else, consensus does not mean you argue for every comment, every dotted I, and every word choice, it means that we have a set of recommendations we can carry forward that represent the will of the taskforce and does not engender strong disagreement.

I think those were all the key considerations. I think Gillian had a suggestion for a glossary. I think if there are terms that we want to define and make sure that they are very clear, we should be doing that. And then, in general, if there are recommendations that are in the spreadsheet that people disagree with strongly, and we have heard some of those, for example, the division of labor between syndromic surveillance and ECR or ELR, the notion of broad, anonymized, deidentified sweeps versus information that is narrowly targeted for case investigation and is personally identifiable. When we hear those disagreements, please raise your hand and express your disagreement. I do not think this is a shy group, and we do want to make sure that if there is anything that we are proposing carrying forward to the transmittal that people do not think is appropriate to carry forward to the transmittal, we definitely want to hear about that as early as possible. Gillian, anything else I missed in terms of that recital of process?

Gillian Haney
No, I think that is good. There is a question from Hans, just to clarify the color coding.

Arien Malec
Yes. The updated clarity of color coding: We have done a revision of the wording here. Green means we are locked in the spreadsheet as we move to the transmittal working document, and so, there will be opportunity to put comments onto the transmittal working document. I do not know if we have publicized the transmittal document broadly to the group, but we will. As I think people can appreciate, we have been so heads-down doing these hearings and getting the Q&A, and then going through the rather shallow dives.

Yellow means we have the work in progress, we have discussed it, it is still in progress, red is a duplicate, and the default, nonshaded color means that we have not yet gone through a deep dive. Hans, hopefully that addresses your question.

Gillian Haney
Thanks for that, Arien, and I also just want to note that we spent a lot of time trying to level set in terms of the criteria that we are working with and what the complexities of each of those data streams are, and we have not really had a lot of opportunity to really start diving into proposed recommendations and some of the comments. So, we have one more criterion, which is healthcare surveys, to address next week, and then we will be full speed ahead in and in discussion mode. Thank you.

Arien Malec
Jeff asked about public comment and public availability. Our intent is to take the draft transmittal letter and make the then-current version available in the meeting materials for the meeting. This document is a fast-moving document, so there is no really good mechanism for locking it down and providing a copy of it. It really is an input tool. But, as we get to draft transmittal, we do intend to take the draft transmittal and publish the then-current version as meeting material. It will be out of date by the time we end a meeting, but we can catch up with it by the next meeting, so for folks who are not able to attend these meetings but want to get a sense for what the current state of discussion is, we do intend to make that draft transmittal available. Yellow means that we are in progress in the conversation. There is a helpful instruction sheet on Tab 1. All right. So, let us pick a topic. Can you hit the drop-down for a second, Liz? The other one.

Gillian Haney
There was one point that I put in, sort of an overarching comment, that there are places that public health is referred to as “public health stakeholders,” and we are really public health authorities because we have legal responsibilities, and I think that there is an official CMS term as the designated public health authority, so I would like to recommend that we use that language instead of “stakeholder.”

Arien Malec
Gillian, I am happy to use whatever language you think is appropriate. I meant to be inclusive of CSTE, AIRA, and other national organizations of public health authorities who have important input but who are not themselves legally designated public health authorities, as far as I understand.

Gillian Haney
Got it. Yeah, I think there are a couple places where we can reflect that nuance.

Arien Malec
Cool. So, if you can come up with alternative language, let’s just be consistent and draft it in consistently, or define a term and make sure people are aware that we still expect CDC to consult with national organizations, etc. Should we go to syndromic surveillance? I do not think we have hit syndromic yet.

Gillian Haney
Sounds good.

Arien Malec

All right. Let me get my chat disposed of. So, this topic, which engendered a fair bit of discussion and lack of consensus, is the topic that there is overlap between syndromic surveillance and other forms of PHI-carrying data reporting, and I think we heard from the public health stakeholders that there was a pretty profound disagreement with the notion that we should be treating these two classes of information equivalently. I am going to try to see if I can represent the sense of the public health community, which is that syndromic surveillance is, necessarily and by design, noisy, it is deidentified, it is used for identifying hypotheses and possible trends, the fact that it is large aggregates of lots of noisy data and lacks the precision of ELR, ECR, etc., is by design, and it would be problematic to try to reconcile those two pieces of information because one is designed to be anonymized and deidentified in most cases.

I think some folks are going to remind us that in some states, there is collection by policy of non-deidentified data, but it is deidentified at some stage in the pipeline, and that the data that informs, for example, case investigation is necessarily and by design very detailed and very precise, and also lags the case by some period of time because it is precise. Because of those two things, there really is no need to harmonize the data between those two views. Ike, you have a question.

Steven Eichner
Not so much of a question, but I was thinking about this yesterday as I was looking at a presentation from the Sequoia Project, and it laid out the idea on the healthcare provider side that there are specialty systems within a hospital that may focus on things like oncology, medication administration, or other practice-specific activities within the hospital environment. It occurred to me that we can describe public health systems in the same type of way as we are looking at specialty systems within the overarching public health umbrella, looking at things like syndromic surveillance, case investigations, and other activities that are not just data, they are programmatic activities within the public health domain, and just like in the private healthcare provider sense, you might not have the exact same data you want between an oncology system and a medication administration system. It is a direct parallel with data needs on the public health side.

Arien Malec
Ike, that brings up another point that I forgot to mention, which is what would we propose certifying…and this is going to turn into a very short history lesson, but the EHR certification program started as a big-bang functional certification program, and has evolved to be a modular, interoperability-focused certification program. It is not always perfect, does not always get to that state of ideal, but that has been the general evolution, and the way the certification world has evolved is that we certify to interoperability standards and associated implementation guidance with certification criteria, and then, some other federal authority, not ONC, attaches certification criteria to programmatics and provides flexibility to providers and hospitals to assemble technology to address the needs of their programmatics with certified technology.

I would anticipate the same thing happening for public health. We would certify a syndromic surveillance interoperability criterion. Technology vendors, public health developers, etc., would be free to adopt those certification criteria and be certified for the components where they require a syndromic surveillance interface. We would not be certifying syndromic surveillance systems or the functionality and needs of those systems, we would be certifying to the interface specification, both content and semantics. And then, CDC would attach, for example, requirements to use certified technology for syndromic surveillance grants, at which point, and I have some language in the spreadsheet to try to be a little more precise here, public health authorities would assemble the technology fit-for-purpose consistent with their policies out of certified

technology, choosing, in some cases, to self-certify the implementation of a build. So, Hans is our resident expert on certification, but also was the originator of this item, so, Hans, we will go over to you.

Hans Buitendijk
Thank you, Arien. I just wanted to follow up a little bit more on some of the discussion around deidentified data, and clearly, that makes it different than ELR/ECR and has a different nature in it. No argument there. But, there are situations that there are directives out there from jurisdictions to include PHI in syndromic surveillance and continue to report that way. So, there is this element of not strictly deidentified, more chatty, etc., which actually still may have some optimization opportunities with others, maybe not specifically ECR, but it might be with SANER or some combination. There is still a potential question, at least, around how we deal with deidentified data and if there is a need for a complete record, or is it just the events, and that is a different story?

But, there is that element of PHI that does trickle into syndromic surveillance, which maintains, then, an underlying question of in those scenarios, are we really using optimized flows for that, and are we starting to mix purposes as PHI is flowing into the transactions? If there is strictly no PHI included in a transaction, I understand the other arguments better, but as there is PHI data flowing in various instances into syndromic surveillance, that still begs the question of if we are using the optimized flows there. So, maybe we need to narrow it and have it as something to be explored still as an optimization down the line, perhaps a couple of different ones here.

Arien Malec
Got it. Aaron appropriately points out that syndromic surveillance, by definition, is intended to be broad and all-encompassing.

Hans Buitendijk
Which is fair.

Gillian Haney
Just to make that point a little bit expressively, I just would add that we are using syndromic surveillance for injury surveillance, for example, looking at suicides, looking at motor vehicle accidents, looking at opioid overdoses, whereas electronic case reporting is very disease-specific, ranging from a specific cancer to something like salmonellosis, so there are really two very, very different data streams, and sometimes we attempt to try to marry them up.

Arien Malec
Maybe the consensus here is we should be aligning the syndromic surveillance implementation guide to other standards and to USCDI, not to marry up data or for any purpose like that, but simply to lower the implementation burden for implementing to the syndromic surveillance guide, but I have not heard that implementing the syndromic surveillance guide is generally problematic anyway because it uses a pretty standard ADT feed, and I have not heard anything about the burden of implementing the syndromic surveillance guide, but that would be the one argument I could see, is if we are requiring totally different data in the syndromic surveillance guide, but it is actually the same data that we require in USCDI in different contexts, we should probably harmonize those two guides.

Hans Buitendijk
The USCDI is not quite a guide, it is more a set of data with a scope.

Arien Malec
Understood, but you get my point, that if the underlying data model that underlies syndromic surveillance is that radically different from the underlying USCDI V.3 data model, then by definition, the implementation guides will have the same data, but represented differently, which will cause an implementation burden, but again, I have not heard that as being a major concern from implementers.

Hans Buitendijk
No, not at this point in time. There is a general longer-term opportunity that data is consistently represented, whatever it is, to cross whatever standard is used.

Arien Malec
Good, okay. So, Hans, would you mind taking another crack at this one and really focus, as we continue to maintain the syndromic surveillance guide, on seeking opportunities to align to common standards?

Hans Buitendijk
I am happy to. There is one question that I raised that has not been addressed yet: How to consider these situations where PHI does start to trickle into syndromic surveillance transactions. How do we consider that? That is where the lines are starting to get blurry. I understand fully the variety of triggers. That is not the same as ECR. Clearly, ECR triggers are expanding as well. There is a method that is starting to evolve out of the variety of transactions that we have, whether they are reportable conditions for ELR, for ECR, or for syndromic surveillance. There is that knowledge base about when this trigger happens, I want to get this set of data that, depending on the circumstance, can be communicated, identifiable or de-identifiable, and the lines can shift based on the types of letters of directive, that type of common approach where we can optimize the data flows more consistently. As you all pointed out, whether that is aligning with USCDI, FHIR, or something else there, that consistency can help tremendously improve on the type of exchanges that we have.

Arien Malec
Got it. Hans, let me repeat back what I am hearing you say, which is during the pandemic, there were cases where local jurisdictions used the existing syndromic surveillance… So, first of all, there has been a point that many of our public health practitioners have pointed out to us, that by state law, the anonymization or deidentification of syndromic surveillance data varies, and there are cases where it is deidentified from origination, there are cases where it is processed in the locality and then deidentified prior to streaming up to CDC and to BioSense 2. The second point that you are making is there were cases during the pandemic where we sought to use the existing feeds because they were up and running to collect additional triggered information in ways that maybe did overlap with EICR or were capturing additional contextual information at a population level, and both Ike and Gillian are able to answer this question.

Hans Buitendijk
And just to clarify, not specifically COVID or the pandemic necessarily. I am looking at one that would be August of 2022. So, from that perspective, I am not sure whether that is pandemic-related or whether that is another purpose, but it is certainly recent.

Arien Malec
Got it. Ike?

Steven Eichner
Two cases. First, I think looking at jurisdictions, they do have the right, and potentially different interests, to provide different services to their communities, so in some cases, they may need identifiable information in support of other services. Also, I think as we are more holistically looking at the data, there does need to be alignment between the data that is being included in submissions and USCDI and ensuring that there is consistency on a go-forward basis that the standards are not outpacing the availability of data. That would also apply to things in SVAP. We cannot get ahead of ourselves in terms of looking at what is certified and what is not certified because as soon as we have that difference, we are going to break interoperability again.

Arien Malec
Thank you. Gillian?

Gillian Haney
Regarding the issues around identifiability, I would classify syndromic surveillance as a partially deidentified data set. It does contain some PHI in there, and there also are some jurisdictions that do request a fully identified data set that are sent before stripping them of some of those identifiers before going to CDC, and there are legal privacy reasons within the states for doing that. So, I think that the authority of public health…we are getting into some legal issues in terms of what information we can share with our federal partners and how syndromic surveillance is used as well for noninfectious diseases. There are legal constraints in terms of what can be reported and when something becomes a cluster that will enable it to be able to obtain further identifiable information. The legal authority with electronic case reporting is very straightforward in terms of the access to fully identifiable information, whereas with syndromic surveillance, it is a different set of rules that are in place.

Arien Malec
We are at risk at this point of beating this particular horse. Where I am hearing consensus is it would be appropriate to make sure that our ongoing reviews and maintenance of the syndromic surveillance implementation guide be kept consistent with the general standards ecosystem to reduce implementation burden. Where I hear strong disagreement is that we should explicitly design syndromic surveillance interfaces to better harmonize with ELR or EICR for the purposes of data reconciliation.

Then, I am hearing some emerging public health use cases to go to some hybrid or more sophisticated event-based notification systems that get more granular information in some situations, and this is either going to go in the realm of there is an emerging public health use case and ONC and CDC should assemble and coordinate the creation of appropriate standards and certification guidance or this goes into states and localities have broad legal authority, and what we are doing is designing a national floor, not creating a machine that can address all state-by-state variation, but hopefully, by creating a national floor that is higher than the current national floor, we have significantly reduced the need for state-by-state variation. That is my recitation of what I believe is the consensus of the group. I think Steven and Hans had some good comments in terms of the standards alignment point. I guess I would ask if we could do another pass of this

recommendation in ways that are more targeted towards standards alignment and less targeted for alignment of data for the purposes of downstream reporting. Hans, is that something you can do?

Hans Buitendijk
Yes, and I also heard the term "event-based reporting." I like that. There is quite a variety of them out there, whether they are ECR-like, ELR-like, or syndromic-like, so I think we can work with that to pull something together.

Arien Malec
Perfect. So, if you could draft a recommendation there for consideration in terms of "There is this emerging use case, and it might be appropriate for ONC to work with federal partners to convene stakeholders to yada, yada, yada." All right. Okay, let's go on to our next one. So, this is our general note that we have named standards in certification criteria that may not be the latest version, and we should update to the latest version. We have seen this comment in a number of places. Strong opinions, disagreements?

Gillian Haney
I cannot fully see what Aaron's comment is. Thank you.

Arien Malec
So, I think there is a cautious belief that we should support the advancement of standards, but also be aware of the burden of implementation of new versions of standards, and make sure that we are not implicitly creating unfunded mandates on public health or creating updates to standards outside of predictable windows that are aligned with granting or aligned with procurement windows, which, yes, I think Hans or some of our provider organizations could tell you how much work it takes to keep up with a certification program once we have one.

Hans Buitendijk
But once you can align them, it starts to become easier.

Arien Malec
It does start to become easier, but again, the nature of doing a certification program is there is a onetime hit, and then, the more that ONC, which has done a good job with the SVAP, can telegraph via the SVAP stands enhancements and make sure the industry is ready for the next iteration, and if those iteration cycles are relatively predictable, then it does become a little bit more like a machine. Hans, you have your hand up.

Hans Buitendijk
Yeah. Whether this topic is syndromic surveillance or not, it will come back in other ones as well of going to a more current one, whether there is that opportunity to provide a recommendation that it is important to start to look at staying current, recognizing, for all parties across the board, the effort to get up for what value do you get, is that the right time to do? We are going to run into that over the next couple of years with FHIR as well. So, that is an important balance, but at this point in time, the lessons learned from before are is syndromic surveillance ready to move up, or do we say no, it is working well, but in light of the other comments, let's figure that out first before we strongly recommend to go to a more current version in that environment? And that depends on whether we can already get value out of the additional version uptick

in the meantime, and that depends on do we think, from a public health perspective in particular, that it provides content and data that otherwise would not have been as easily able to be obtained.

Arien Malec
When we get to the general section, I have drafted some recommendations talking about the notion of a phased approach, talking about the notion of flexibility. This has been a perennial challenge as we have been doing certification-based upgrades of the HIT system, and I do not think it will be new to ONC, but it has been a topic that we have discussed repeatedly, and I wanted to make sure that we memorialized it as a recommendation. Why don't we go on to the next one? So, Hans, I think you and Steven co-collaborated on this one. Could we get your thoughts about whether we recommend updating to the latest or whether we need an omnibus updating to the latest and aligning standards recommendation?

Hans Buitendijk
This was on the Adopted Standards. Ike, do you want to comment on how the conversation was and how we create a balanced approach?

Steven Eichner
Sure. For the Adopted Standards Taskforce, we looked at 55 standards that were included in regulation and are the responsibility of ONC and made recommendations to ONC through HITAC looking at whether those standards should be maintained or retired. For both the standards, syndromic surveillance included, we recognized that the current standard in place may be a little bit out of date, and there may be additional standards or a new standard that is ready to be implemented, but there needs to be regulatory action taken to move that into regulation at the next available time or the next time the regulations get opened for change. Syndromic surveillance was one of those that was included in that space, but again, the necessary resources have to be available for public health to implement, as well as providers to adopt. That is pretty much where it is at.

Arien Malec
Okay. So, maybe we could ask if we can create an omnibus recommendation here. I remember overseeing this, that the Adopted Standards Taskforce did a lot of good work in already doing some of this pre-analysis. If we could do a general recommendation to this nature rather than area by area, that might be easier to read, but again, I defer to the folks who are willing to put in the work to do this work. Otherwise, we will just carry these recommendations forward.

Steven Eichner
I think it could be done as a single recommendation, again, recognizing that there have to be the right resources in place to adopt, and if we are looking at doing things out of cycle, we need to be cautious about backward compatibility and breaking systems. How do we certify an SVAP-implemented activity against what criterion, and what happens if it is done off cycle?

Arien Malec
Absolutely. Again, when we get to the recommendation in the general recommendations, which maybe we should go to after we do this one, you will see that, as I said, I have tried to draft some recommendation text to address that point that we have been discussing. Okay, the next one is from Les, which is on SANER and situational awareness, so we are going to punt this one from "syndromic surveillance" and move it to

"other," and then, we already have an "other" section here. So, Les, this is not by way of invalidating this point, but just by way of saying that the general point here is that we have identified two areas of public health standards implementation guidance and potential certification where there are data flows, but as yet, no adopted standard. One of them is vital health statistics, and the other is this one of situational awareness. So, we are going to move this one to the "other" category, and then address it in that context.

So, Les, point on communication infrastructure for disaster and situational awareness. I would say the general point in situational awareness belongs in the "other" category. I believe telecom communication granting would be outside of our scope for reviewing the F criteria and related criteria for public health data flows, so we can bring it up, but I believe this would be an out-of-scope item. Oh no, we have violated our rules! All right. Hans notes that we have, in the syndromic surveillance value set list, lists that are not as granular as capture in systems that are required by jurisdictions, and we should align on terminology sets for syndromic surveillance as well as for other implementation guides that were drawing from common value sets and have the ability to create appropriate value subsets. Did I capture your comment correctly, Hans?

Hans Buitendijk
Correct, yes. We are finding in a number of instances that a common set would be helpful.

Arien Malec
Yup. Any other comments on this point, or should we proceed on?

Hans Buitendijk
Maybe one additional comment that has both a consistency of reporting at the initial report, but then, also the downstream analytical aspect of having consistency wherever you can on analysis.

Arien Malec
Yup. And so, again, this is the general point that in areas where, even if the need is different and even if the context for use is different, to the extent that we can align the underlying standards, we are reducing implementation burden. Let's go to the next one, which, Hans, is yours. Maybe we can just defer over to you.

Hans Buitendijk
Are you looking at 57 or 58?

Arien Malec
Fifty-eight.

Hans Buitendijk
So, this is a timing question, and it goes back to if that is okay or not, but some of the data that is desirable for syndromic surveillance is not necessarily at the time of an ADT event. It becomes known later, and therefore, you have that question of how you gather that, include it, and trigger it to get the appropriate amount of data that is of interest for that particular trigger that is made available. So, that is a challenge that goes back, then, to if you are going to split the syndromic surveillance transactions into multiples where

you can get that additional data, and particularly if you are in a deidentified space, now we have the challenge on how to merge them back together after the data is already deidentified.

So, I think it is just pointing out a challenge that we need to get a better understanding and consideration of what data set is relevant and appropriate, recognizing that the registration, admission, and discharge is not always the best time, or it is just not available. It will not become available until later, or it is just not available because it was not provided. That creates some challenges in expectations and content. So, hence the suggestion, and yeah, this needs to flash back to the other one. How can we marry up some of those flows so that data at different stages can be linked back up again? We have had a more in-depth discussion on where there are areas where syndromic surveillance just cannot take advantage of ECR or other identifiable data streams, but are there opportunities there where it can, particularly if it is becoming semi-identifiable or otherwise? So, I think it just is part of this overall. It is not a very optimized flow in light of where the data and when the data is captured and becomes available.

Arien Malec
Yeah, I am going back to Gillian's point that syndromic surveillance is noisy and voluminous by design.

Hans Buitendijk
Right.

Arien Malec
I have not heard public health say, "I would rather get data a little bit later and get more precision on it." Okay, let's move on, then. Standards conflicts. Hans? Oh, I see.

Hans Buitendijk
This is a general thing.

Arien Malec
Yeah, this is your point that there is a base syndromic surveillance implementation guide, and then, there is state-by-state variation. I think our recommendation here would be a request for ONC to convene appropriate work to ensure that the chosen implementation guide truly is a floor guide that raises above the existing floor to reduce state-by-state variation.

Hans Buitendijk
Yes, and here, the reference to ECR is not on the content, it is more of…

Arien Malec
The process, understood.

Hans Buitendijk
…the technique of how you can share the knowledge of who needs what under what conditions so that it becomes easy to stay up to date and to then adjust the content accordingly.

Arien Malec
Yup. And then, 60 is the same point, just at a more granular level of detail.

Hans Buitendijk
Yes, then it is about the data itself. So, what are the triggers, what is the data, what are the variations, is there an opportunity floor? And, we could combine that into one. There is a need for consistent knowledge that we can share maintained, akin to how ECR is starting to do it.

Arien Malec
Sure. Any objections to that point? The general point is that we should be continuing to develop and align the syndromic surveillance, survey STLT needs, and ensure that we have an implementation guide that addresses appropriate variation in order to reduce implementation burden. No objection?

Gillian Haney
I concur.

Hans Buitendijk
I think you can skip 61 because we already discussed it. It is a duplicate.

Arien Malec
Okay. And then, 64, I think, is the point that we were raising previously, that it would be desirable to have a standard by which public health can push alerts to provider organizations or push updates to provider organizations. I do not believe that is syndromic surveillance. I would request that we just retag this one as "other" and discuss it when we get to the "other." Maybe we can move to "overarching" at this point. All right, and we have a lot of "overarching."

Steven Eichner
Arien, there is one thing I wanted to mention. As we are thinking about a central repository of information, I do want to remind folks about Promoting Interoperability and Meaningful Use, that there was originally a requirement that CMS develop a directory of information about public health engagement for Meaningful Use, and there were a couple of different initiatives or efforts put together to develop it, but it was never successful.

Arien Malec
I appreciate that. So, we should have done that.

Steven Eichner
No, it is not better or worse. It is just in the context of Hans's suggestion of looking at developing a national directory or national resource in that space. We do have some history about trying to develop it and recognizing that it can be challenging.

Arien Malec
And again, I think Hans points out that we have a collaboration model in EICR that has been very successful, we have had a collaboration model with AIRA that has been very successful, so, in more targeted areas rather than more general public health information data flows, we have this taskforce, which will hopefully be very successful, but these long-lasting initiatives tend to be more successful when they are more focused on a particular public health need and less successful when they are general informatics

governing societies. That would be the gloss that I would have on it. We do have success models. That is all I am saying.

Steven Eichner
And to pull the curtain back a little bit about looking at EICR work, with any state, there can be an awful lot of effort and there is an awful lot of effort being put forth in coordinating efforts between state and local jurisdictions as well, so it is not whether there is a good model in place, there really are an awful lot of moving parts in that space, that it is not as easy as it might be.

Arien Malec
No doubt. All right, let's go on to overarching No. 1. So, 63: This is the general comment that we have heard, which is the need to capture a floor level of necessary data, the ability to capture updated race/ethnicity data above and beyond the 5+2 OMB race/ethnicity codes, the need to consider certification that is not just on the content, but also on the semantics. We do not have the tag for who put this one together, so I am trying to represent this information. If anybody can volunteer… Les, was this you? Oh, I see. Steve Eichner was the person who represented it. Les, you have a comment.

Leslie Lenert
My comment was do we need to mention CDS Hooks someplace as a place to expand the standards for two-way communication, particularly beyond the notion that it comes back to the mailbox via direct, which then has to get routed? It would seem to me that the two-way communication efforts should encompass CDS Hooks in some way so that it can come to the point of care.

Arien Malec
Yeah, I would generally concur that the appropriate standard for use of decision support for public health should probably leverage CDS Hooks. In the other section, where we are thinking about two-way communication, would you mind just making reference? So, we do not want to make recommendations that ONC use CDS Hooks because we want ONC to be convening folks to appropriately explore the design space, but we can make reference that CDS Hooks is a fit-for-purpose standard for decision support.

Leslie Lenert
Okay, I will go down and add that to the others.

Arien Malec
Cool. And as always, Hans has some additional context here of whether we are doing decision support versus pushing information, and the context for use is going to be different than each of those cases. All right, Steve. Is Ike on?

Steven Eichner
Yes, sir.

Arien Malec
Yeah. I was trying to represent your comments here, but maybe I will let you represent your own comments.

Steven Eichner

I am perfectly content for you to do it, but it is really looking at a focus on certification at the connection points, so, looking at both the sender and the receiver are capable of sending and/or receiving messages as appropriate that are both syntactically and semantically interoperable.

Arien Malec
So, definitely, I think we have broad consensus on that point. Would you mind taking another pass at turning that into recommendations text? So, "We recommend that ONC…"

Steven Eichner
[Inaudible – crosstalk] [01:20:16]

Arien Malec
Yeah, because right now, this list is a set of desiderata, which is great, but we need to be thoughtful about the ONC mechanisms to turn those desiderata into stuff.

Steven Eichner
Lovely.

Arien Malec
Cool, thank you. And then, we have three more minutes. Let's go down one. Whoops, there is a lot more "overarching" here. I thought we were starting pretty far down. Cool, so, Item 5 was mine, so, with nice misspellings in it, "We recommend that any certification of public health interoperability modular…" So, this is the point that we should not be certifying whole systems because in the real world for public health data systems, there is a mix of potential intermediaries who are important in the chain, and Ike points out in the observations that there are local law/policy procurement limitations, etc., so I tried to massage that down to "recommend that any certification criteria for public health data systems interoperability be modular, provide public health authorities maximal flexibility in selecting certified technology, which may be owned, managed, or consumed as a service, and/or through intermediaries, yada, yada, according to legal policy/procurement rules governing public health."

So, hopefully I captured the sense of the taskforce. I am happy to respond to folks who think we could word this better. Hearing none, I do not think we have time for one more. Let us go to public comment, and if we do not get any public comment, we will go to one more.

Public Comment (01:22:38)

Michael Berry
All right. Thanks, Arien, and as Arien noted, we are going to open up our call for public comments. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. So, let's pause for a moment to see if anyone raises their hand. I am not seeing any hands raised, Arien, so I will turn it back to you and Gillian.

Arien Malec
If we do get a public comment in, we are happy to interrupt our deliberations and get the important public comment, but let's go back and pick up one more of these "overarching" or "other" comments. I am making

Liz go through gymnastics here. All right. So, here, I put the comment in, which I think is the same comment that we discussed under 63, disconnected certification interoperability, and I did not do the work of turning this into the "We recommend" text, so, Ike, maybe you and I can collaborate on turning the synthesis of my No. 6 and your 53 into some definitive recommendation text.

Steven Eichner
Absolutely.

Arien Malec
Fourteen, certifying use versus certifying systems. So, it is really the same point that we are making in 6 and in 63, or whatever it is that we are duplicate with, and what we want to certify is that it works in practice and close the gap between certification and use in practice, so I think we can get a harmonized goal here.

Steven Eichner
Arien, on **[audio cuts out] [01:25:03]** one, if I may make a comment, the technique that is being used for current certification is that the software is being certified, not the provider using it, but that there is real-world testing that can confirm that what is actually certified and running in practice works, and one other question, I think, that has been part of that is that trying to certify all of the different users of the software might be a lot harder than having a combination of the software being certified and other elements to make it manageable.

Arien Malec
That is right. Hans, when I am turning these things into recommendations, I am trying to concentrate on process outcomes as opposed to process inputs for exactly that reason. We do not want to make recommendations of things that could be problematic in practice, but I think it would be safe to say that in the EHR certification program, we have sometimes had gaps against the demonstration capabilities of EHRs in a certification program and the on-the-ground capabilities of that software. There have been well-publicized legal cases.

Sometimes, because the certified capability was not actually deployed, and then, often because of the types of data that are collected on the ground, the certification process works only when the stars align and all the data are captured correctly, and in the real world, where you are capturing data in a much messier way or you have older data, the certified capability does not conform to the implementation guide, but definitely, if you can help us with the drafting of this text and make reference to the real-world testing program as well. I think the key things here are we want to certify to semantics, not just to content, we want to make sure our certification program is rigorous and provides a prima facie validation that the certified technology actually is available in practice, and then, we want to enable some level of real-world testing to verify that the certified product works as designed in the field. All right, we have one more minute.

Steven Eichner
This is Steve. I just wanted to get this in really quickly. We need to get better information about what real-world testing is actually occurring on both ends in terms of how the real-world testing is being deployed, who on the public health side, what exact systems are being used on the public health receiving end of it, what exact systems, and what environments are being used in the real-world testing environment. A pseudo-real world deployment in a lab situation with straight code that is straight out of the box may be

performing substantially differently than real real-world testing after it has been installed in the field behind whatever firewalls and things are in place in the real world.

Next Steps (01:28:44)

Arien Malec

Absolutely. Again, I think we are going to have to leave it there because we are at time. Obviously, we have a lot more to go, and again, a reminder that we are going to take most of October to try to go through this information in this level of detail. We will extract recommendations into the formal transmittal draft, we will go through that transmittal as a draft, there will be ample opportunity to cross-reference what is in the spreadsheet to what got into the draft, we will go over it multiple times until we are all sick of it, and then, once we are all sick of it, we will just pass it on through for an exhaustion to the full HITAC. So, I think we are in relatively good shape. We have a lot of work to do, but we are in relatively good shape to be able to get through the final transmittal on the 10th. So, thanks, everybody.

Gillian Haney

Thank you, everyone.

Adjourn (01:29:39)